Annex 1

Specific remarks and demands for amendments to the FDA proposals on registration of food facilities (Section 305 of the Bioterrorism Act 2002)

Docket No. 02N-0276

US and foreign facilities will have to register between 12 October and 12 December 2003 to help counteract terrorist threats or outbreaks of food-borne illness, by determining the source and cause of a problem. The draft law raises a number of concerns:

- The obligation to have a single agent in the US is a matter of serious concern especiallly for small and medium sized companies (SMEs). This requirement does not acknowledge the commercial reality of some German and European producers, who often deal with two or more importers in the USA—because of geographical or product differences—or who operate using different importers case-by-case. It is also possible that products sold to German food retailers are shipped by the retailer to export destinations not previously known to the producer, for example if the retailer regularly re-stocks its outlets in several English-speaking countries from products bought in bulk from German producers. In these cases it is not trivial to assign a single US importer or broker as agent. For the purpose of registering with FDA the necessitiy of having an US agent is not appearant. Registering can be accomplished—via the internet—without any US party other than FDA involved.

- As a matter of fact, as recognized in the notification text, a number of German exporters do not have an agent yet and the additional cost a company will incur for the hiring of an agent may lead to the decision not to enter registration. In practice, SMEs will be most affected by the measure. BVE considers that this part of the text interferes in commercial relations between companies. It should not be compulsory to hire an agent and hence procedures should be made easier for exporters who do not have an agent.

- In many cases, German companies send finished or semi-finished goods or even raw materials only to their own subsidiaries in the US, where these products undergo a more than minimal further processing. The US subsidiary is therefore ultimately responsible for bringing these products into the food chain in the US. Hence, their foreign parent company should not have to register with the FDA.

- In some cases, the foreign facility only packs raw materials previously bought (some on international markets) in order to send them to its US subsidiary for final processing. Under the proposed provision, not only this facility, but also all of its suppliers would have to register with the FDA. Where a company sends unprocessed or minimally processed goods to its own US subsidiary, it is often impossible or at least very difficult to ensure that all of the sending company's suppliers were registered with FDA, as the draft rulemaking stipulates. Still, the

economic consequences of a failure to register for one of the suppliers, i.e. a product detention at the port of entry, would in most cases have to be borne by the sender. In order to avoid these consequences the sending facility would have to make sure that all of its suppliers are registered with the FDA. This would be an extreme administrative burden. Some of the suppliers may be located in other third countries, and it may be very difficult to ensure their registration, to oblige them to register and, lastly, to hold them responsible for not registering, given various and possibly complicated legal systems of the countries in question. Again, this should not be necessary as the US subsidiary's registration should suffice.

- Companies exporting to the US with more than one production site face difficulties in interpreting the rules on registering. Even though FDA has made an effort to define this, it should be spelt out even more clearly which companies or sites have to register. In BVE's opinion it should suffice that solely the parent company registered itself once-and-for-all if it centrally manages all of its prodution plants' exports to the US and takes the responisibilty for these trade flows. In this case it is not necessary for FDA to know the actual production sites of the goods offered for importation. Rather, if a problem is suspected, it is sensible and sufficient for FDA to contact the appropriate responsible person in the foreign parent company who coordinated the shipment.

- BVE also requests consideration and clarification of the requirements for limited quantities of samples (e.g. for market testing or tasting. Any requirement to comply with the registration provision before their importation could create a serious impediment to the introduction of new products or promotion of products already in the market.

- Last but not least, in order to get the system operational step-by-step and not disrupt trade flows a period of exemption from prosecution should be foreseen for operators who do not register correctly (or at all) in time.